

## OPHTHALMIC DEVICES PANEL of the MEDICAL DEVICES ADVISORY COMMITTEE

Hilton Washington DC North/Gaithersburg 620 Perry Parkway, Gaithersburg, MD

P120023 KAMRA™ Corneal Inlay, Model ACI 7000 AcuFocus, Inc.

June 6, 2014

**Panel Chairperson**Neil M. Bressler, M.D.

08:00 a.m.

**Designated Federal Officer** 

Natasha G. Facey

Panel Introductions

Call to Order

Conflict of Interest Statements

08:15 a.m. Sponsor Presentation

09:45 a.m. Q&A Sponsor

10:00 a.m. Break

10:15 a.m. FDA Presentation

11:45 p.m. Q&A FDA

12:00 p.m. Lunch

01:00 p.m. Open Public Hearing\*

02:00 p.m. Q&A Open Public Hearing

02:15 p.m. Panel Deliberations

03:30 p.m. Break

03:45 p.m. FDA Questions

05:30 p.m. FDA and Sponsor Summations

05:40 p.m. Panel Vote

06:00 p.m. Adjournment

<sup>\*</sup> Open Public Hearing – Interested persons may present data, information, or views, orally or in writing, on the issue pending before the panel. Scheduled speakers who have requested time to address the panel will speak at this time. After they have spoken, the Chair may ask them to remain if the panel wishes to question them. Then the Chair will recognize unscheduled speakers as time allows. Only the panel may question speakers during the open public hearing.